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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
YOUNG, SHAWQUIA	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/566,164	MERCE VIDAL ET AL.	
	Examiner	Art Unit	
	SHAWQUIA YOUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 45* is/are pending in the application.

4a) Of the above claim(s) *14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,17 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 and 45 are currently pending in the instant application. Applicants have cancelled claims 18-44 and 46-72 in an amendment filed on July 20, 2009. Claims 1-13, 17 and 45 are rejected and claims 14-16 are withdrawn from consideration in this Office Action.

I. *Response to Arguments*

Applicants' amendment, filed July 20, 2009 has overcome the rejection of claims 1-13, 17, 18, 45 and 46 under 35 USC 112, second paragraph as being indefinite for the term "substituted"; the rejection of claims 1-12, 17, 18, 45 and 46 under 35 USC 112, first paragraph for not being enabled for a solvate of a compound of formula (Ia); the rejection of claims 18 and 46 under 35 USC 112, second paragraph as being indefinite for claiming genus diseases that are not clearly defined in the specification; the rejection of claims 18 and 46 under 35 USC 112, first paragraphs as failing to comply with the enablement requirement and the objection to claims 4-7, 11-13, 17, 18, 45 and 46 as being improper multiple dependent claims. The above rejections and objection have been withdrawn.

Applicants' arguments have overcome the rejection of claims 1-7 under 35 USC 102(b) as being anticipated by Semmelheck, et al.; the rejection of claims 1-13, 17, 18, 45 and 46 under 35 USC 103 as being unpatentable over Li, et al. and the rejection of claims 1-13, 17, 18, 45 and 46 under 35 USC 112, second paragraph as being indefinite

for the limitation "a saturated or unsaturated, optionally at least mono-substituted cycloaliphatic radical....". These rejections have been withdrawn.

The rejection of claim 13 under 35 USC 112, first paragraph for not being enabled for a solvate of a compound of formula (Ia) has been maintained because Applicants have not deleted the term "solvates" in claim 13 and have not provided evidence that the instant specification is enabled for "solvates" of the claimed compounds.

Applicants traverse the restriction requirement sent by the Examiner and argue that the special technical feature of the claimed invention does provide a contribution over the art. However, the Examiner wants to first point out that the special technical feature of the claimed compounds do not include the variables which can be defined as various groups. Therefore, the prior art reference (EP 0815861) cited by the Examiner is proper because it does teach the special technical feature of the claimed compounds which is the 1-substituted indole-4-sulfonamide core.

Further, the Examiner wants to point out that it clearly states under rule 13.2, "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Applicants' special technical feature which is based on the structure of formula Ia does not make a

contribution over the prior art (See, EP 0815861) and therefore lack unity of invention. The restriction requirement is deemed proper and made final and the pending objection of the elected claims as containing non-elected subject matter has been maintained.

Applicants' traverse the ODP rejections of claims 1-13, 17, 18, 45 and 46 as being unpatentable over claims 1-14, 18, 19, 46, 47 and 74-93 of copending Application No. 10/566,094; claims 1-14, 18, 46 and 75-91 of US Patent 7,414,070 and 1-18, 46 and 74-100 of US Patent 7,462,640. Applicants argue that the compounds in the copending application 10/566,094 and the patents are positional isomers of the claimed compounds and are no encompassed by the claimed invention. However, the Examiner wants to point out that it was established in In re Jones, 162, F. 2d 638, 74 USPQ 152 (CCpA 1947) that compounds which differ only in the placement of substituents in a ring system is not novel absent unexpected results. It would have been obvious for one of ordinary skill in the art to change the position of the sulfonamide group on the phenyl ring of the indole moiety with a reasonable expectation for success. Therefore without any unexpected results the instant compounds are considered obvious over the above copending application and issued patents. The ODP rejections have been maintained.

II. *Rejection(s)*

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13, 17 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 18, 19, 46, 47 and 74-93 of copending Application No. 10/566,094; claims . Although the

conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-5, 9, 10, 15-19, 21-25 and 30 provide products which are obvious variants with the copending application's claimed products and provide species in the instant claims which render obvious the copending application's claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-13, 17 and 45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 18, 46 and 75-91 of US Patent 7,414,070 and 1-18, 46 and 74-100 of US Patent 7,462,640. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-13, 17, 18, 45 and 46 provide products which are obvious variants with the copending patent's claimed products and provide species in the instant claims which are obvious over the copending patent's claimed invention.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the

specification, while being enabling for a compound of formula (Ia) or physiologically acceptable salts of said compound does not reasonably provide enablement for a **solvate** of a compound of formula (Ia). The specification does not provide sufficient guidance nor does it enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

The nature of the invention

The nature of the invention is a compound of formula (Ia) or one of its stereoisomers, its racemate or a salt. There is no teaching of solvates of the compounds of Formula I in the specification.

The state of the prior art and predictability or lack thereof in the art

It is the state of the prior art that the term "solvate" found in the claims is defined as a compound formed by solvation (the combination of solvent molecules with molecules or ions of the solute. It has been estimated that approximately one-third of the pharmaceutically active substances are capable of forming crystalline hydrates. Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compound (See *Vippagunta, et al.*)

The scope of "solvate" is not adequately enabled or defined. Applicants provide no guidance as how the compounds are made more active *in vivo*. Solvates and hydrates cannot always be predicted and therefore are not capable of being claimed if the applicant cannot properly enable a particular hydrate or solvate.

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance present in the specification or working examples present in the specification are that defines or relates to what solvates are being included in the elected invention. The term "solvates" is discussed on page 39 of the specification and reads on the following:

"The solvates, preferably the physiologically acceptable solvates, more preferably hydrates...".

The breadth of the claims

The breadth of the claims is a compound of formula (Ia) or one of its stereoisomers, its racemate or a salt or a corresponding solvate thereof.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with various solvents without any direction as to what compounds form solvates with which solvents.

The level of skill in the art is high without showing or guidance as to how to make solvates of a compound of formula (I) it would require undue experimentation to figure out the solvents, temperatures and reaction times that would provide solvates of the above compounds.

To overcome this objection, Applicant should submit an amendment deleting the term "solvates".

IV. Objections

Claim Objection-Non Elected Subject Matter

Claims 1-13, 17 and 45 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

V. Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626